

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1315]

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Certifier	Monon Oliver

Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#108) entitled "How to Use E-Mail to Submit Information to the Center for Veterinary Medicine" (CVM). This guidance provides guidelines on how to submit information to CVM as an e-mail attachment by Internet. These electronic submissions are part of CVM's ongoing initiative to provide a method for paperless submissions. This guidance implements provisions of the Government Paperwork Elimination Act (GPEA).

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 29, 2000 (65 FR 40109), FDA published the notice of availability of the draft guidance entitled "How to Use E-Mail to Submit information to the Center for Veterinary Medicine" giving interested persons until August 28, 2000, to submit comments. We received no comments.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records; electronic signatures regulation. This rule in part 11 (21 CFR part 11) provides for the voluntary submission of parts, or all, of regulatory records in electronic format without an accompanying paper copy. This rule also established public docket number 97S-0251 to provide a permanent location for a list of the documents or parts of documents that are acceptable for submission in electronic form without paper records and the agency units to which such submissions may be made. CVM will identify in this public docket the types of documents which may be submitted in electronic form. In addition, CVM will identify those documents in guidances or regulations. This docket is accessible on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm>. The GPEA of 1998 (Public Law 105-277) requires Federal agencies, by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, when practicable.

CVM accepts certain types of submissions by e-mail with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by § 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the electronic records; electronic signatures regulation. This guidance outlines general standards that should be used for the successful electronic submission of any information by e-mail.

II. Significance of Guidance

This Level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The guidance represents the agency's current thinking about using e-mail to submit information electronically. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

In the notice announcing the availability of the draft version of this guidance, FDA published notice of the proposed collection of information related to the guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance documents. No comments were received on the estimated annual reporting burden. The annual reporting burden estimate of 140 hours therefore remains unchanged. In the **Federal Register** of September 21, 2000 (65 FR 57192), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance document have been approved under OMB control number 0910-0453. This approval expires November 30, 2003. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

IV. Electronic Access

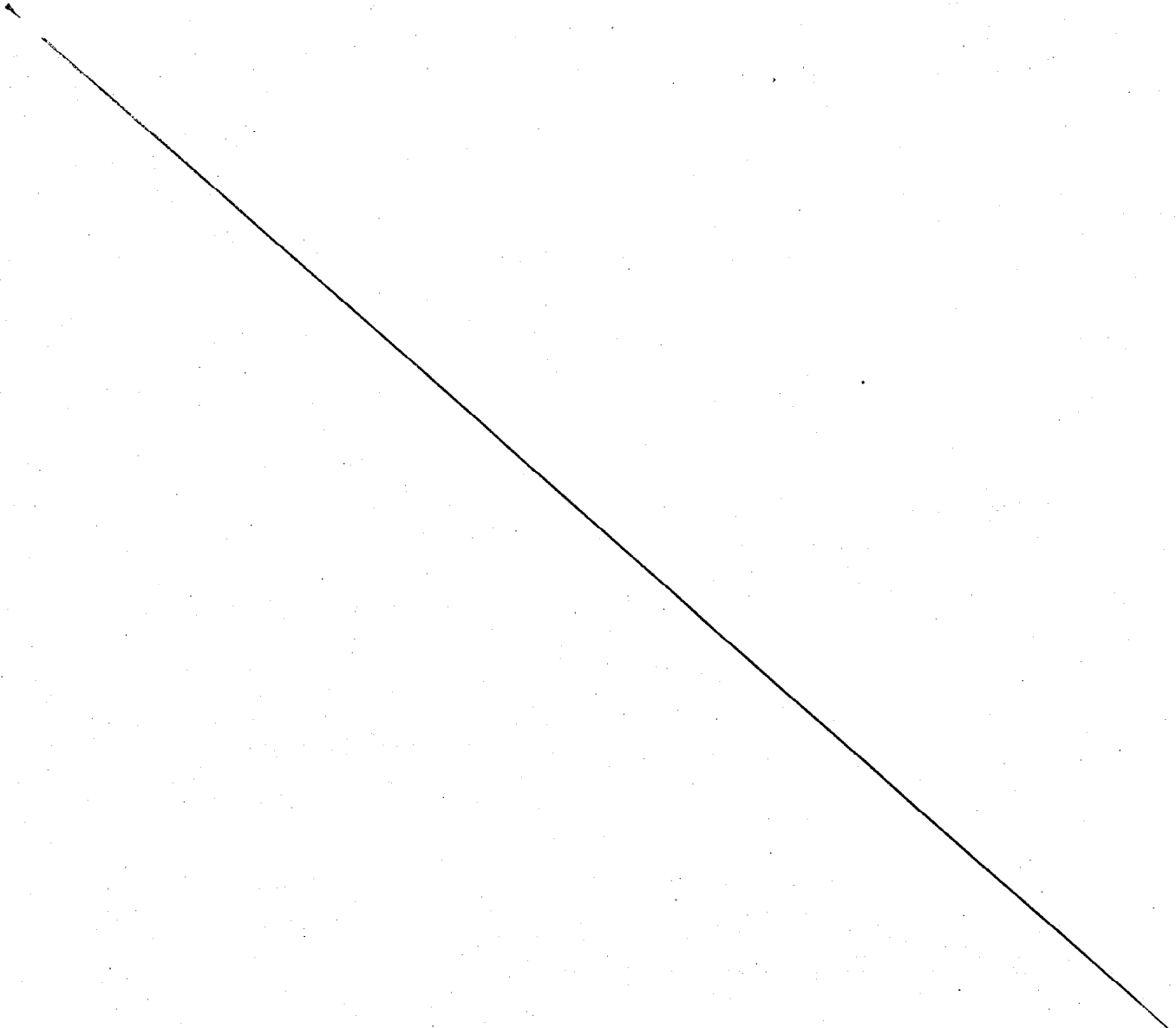
Persons with access to the Internet may obtain the document at <http://www.fda.gov/cvm>.

V. Comments

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. FDA will periodically review the

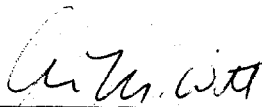
comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



Dated: February 14, 2001
February 14, 2001

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Ann M. Witt
Acting Associate Commissioner for Policy

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